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10/530,824	10/19/2005	Lynne Rainen	P-5729	7737

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EXAMINER	
UNDERDAHL, THANE E	
ART UNIT	**PAPER NUMBER**
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,824	RAINEN ET AL.	
	Examiner	Art Unit	
	Thane Underdahl	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/19/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-76* is/are pending in the application.

4a) Of the above claim(s) *28-76* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-76* is/are rejected.

7)☒ Claim(s) *12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2005* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Restriction/Election

Applicant's response to the species election without traverse filed on 11/19/07 is acknowledged. The applicant elected Group I which includes claims 1-27. Claims 28-76 are withdrawn as being to non-elected subject matter.

Claim Objections

The Examiner objects to the limitation of claim 12 that "the caspase inhibitor inhibitors one or more cysteinyl aspartic acid proteases". This is not further limiting since caspases are cysteinyl aspartic acid proteases.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 16 includes the limitation that "the stabilizing media is trehalose". Trehalose alone is a sugar and while it can be a component of culture media it is not obvious to one of ordinary skill in the art how it can be the only component of the media. This claim will read that the stabilizing media comprises trehalose. Claim 21 contains the language of "partially evacuated". This term is indefinite since it is unclear what is being evacuated from the tube.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 10, 11, 12, 14, 15, 17, 18, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Keana et al. (U.S. Patent # 6184210). These claims are to an apparatus for containing a biological sample. This container has a reservoir portion for receiving a biological sample and a stabilizing agent. The stabilizating agent comprises a caspase inhibitor. The container can be provided in many forms including microtiter plates bottles, vials syringes, multiwell plates. The stabilizing agent is in the form of a solution or suspension or lyophilized material. The apparatus comprises a carrier media and stabilizing media. The apparatus further comprises at least one antioxidant or reducing agent or buffering agent.

Keana et al. teach an apparatus for culturing HeLa cells in a 12 well microtiter plate with Minimal Essential Medium with 2 mM glutamine that serves as a carrier and stabilizing media for the cells (Example 21). The media also includes several peptides that are known caspase inhibitors (Example 21, col 18, lines 55-60, see also Example 23). The caspase inhibitor can lyophilized and added to solution (col 11, lines 1-5). The preparations of the caspase inhibitors can include antioxidants (col 13, lines 45-50) and buffering agents such as HEPES and reducing agents such as glutathione (Example 23).

Therefore the reference anticipates claims 1, 2, 10, 11, 12, 14, 15, 17, 18, and 19.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 10-12, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Charlton with support in light of Wilhelm (Immunology Letters, 1997).

As previously mentioned above these claims are to an apparatus for holding a biological sample comprising a container and stabilizing agent in a reservoir for holding the biological sample. This stabilizing agent is a caspase inhibitor. The container can be a tube with a first and second end comprising a separating member in the container.

Charlton teaches a tube for collecting biological samples comprising a tube with a first and second end. The tube has a membrane, which serves as a mechanical separating element, that is partially coated with sodium azide (col 5, lines 5-10), which is a known inhibitor of caspase as supported by Wilhelm et al. (page 57, col 2). The sodium azide is located in a dry form on the filter (col 4, lines 35-36). The tube has a cap to seal the first end (see Figures 6 and 7, #30). Also Figures 6 and 7 show the tube is partially evacuated. Therefore the reference anticipates claims 1-7, 10-12, 20.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 10-15 and 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keana et al. as applied to claims 1, 2, 10, 11, 12, 14, 15, 17, 18, and 19 above and in further view of the following arguments.

The description and rejection of claims 1, 2, 10, 11, 12, 14, 15, 17, 18, and 19 are listed in the 35 U.S.C § 102(b) rejection above. Claim 3 limits the container is a tube having a first end and a second. This first end can be closed. The tube is partially evacuated. Also the stabilizing agent comprises more than two caspase inhibitors and further comprises anticoagulants.

While Keana et al. teach that their apparatus is in the form of multi-well plates. It would have been obvious to someone skilled in the art to use test tubes such as shaking tubes or flasks. These are well known in the art as art recognized equivalents for the purpose of culturing cells (M.P.E.P. § 2144.06). Test tubes such as the shaking tubes used for cell culturing are inherently sealed on one end and can be capped or sealed to prevent the spillage of the culture media during the experiment. Also one of ordinary skill in the art would also not fill the tube completely to capacity so not to cause spillage. Therefore part of the tube will be empty of media and thus evacuated of media.

Futhermore Keana et al. teach multiple caspase inhibitors (Summary of Invention). M.P.E.P. § 2144.06 states

> "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Therefore it is *prima facie* obvious to one of ordinary skill in the art to add more of the caspase inhibitors of Keana et al. to their apparatus.

Also Keana et al. teach in example 23 that their multi-well apparatus can comprise the anticoagulant EDTA. EDTA and Heparin are well known to those of ordinary skill in the art as anticoagulants.

Therefore the references listed above renders obvious claims 1-3, 10-15 and 17-24.

Claims 1-3 and 10-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keana et al. as applied to claims 1-3, 10-15 and 17-24 above, and further in view of Eagle et al. (Carbohydrate Utilization by Cell Cultures, 1958).

Claim 16 limits that the stabilizing media contains trehalose. While Keana et al. teach stabilizing media that contain other sugars to grow HeLa cells, they do not teach trehalose. However HeLa cells are often grown in media with trehalose as supported by Eagle et al. (pg 551, Methods and pg 552 Table 1). It would have been obvious to someone skilled in the art to use trehalose in the apparatus of Keana et al. since using trehalose is a known element using to grow HeLa cells (KSR International Co. v.

Teleflex Inc., 550 U.S.--, 82 USPQ2d 1385 (2007)) . Therefore the references listed above renders obvious claims 1-3 and 10-24.

Claims 1-3, 10-15 and 17-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keana et al. as applied to claims 1-3, 10-15 and 17-24 above, and further in view of Swiderek et al. (U.S. Patent # 5932473).

Claims 25-27 limit that the anticoagulants are spray dried onto at least a portion of the interior wall which is a product by process limitation. M.P.E.P. § 2113 states "product-by process claims" such as this "are not limited to the manipulations of the recited steps, only the structure implied by the steps" as cited below:

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

Therefore the structural limitation considered in this claim is that the anticoagulants are coated, by any process, onto the surface of the apparatus absent any teaching of criticality of structural benefit obtained by spray drying.

While Keana et al. teach that EDTA is included in their multi-well apparatus for holding biological samples. A person of ordinary skill in the art would recognize that a test tubes could be substituted for the wells of a multi-well apparatus such as a

microtiter plate. One of ordinary skill in the art would also recognize that EDTA and heparin are known anti-coagulants. What Keana et al. does not teach is these anti-coagulants are spray-dried on the interior portion of the wall of the apparatus. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Swinderek et al. They teach that their multi-well plates for holding biological samples can be coated with EDTA (Example III).

It would have been obvious to someone skilled in the art for Keana et al. to coat their multi-well plates with EDTA as taught by Swinderek et al. The reason for the obviousness is that both teach the use of multi-well plates for holding biological samples. Using a known modification or technique to improve a similar apparatus or composition used for the same purpose is obvious (KSR International Co. v. Teleflex Inc., 550 U.S.--, 82 USPQ2d 1385 (2007)). Therefore the references listed above renders obvious claims 1-3, 10-15 and 17-27.

Claims 1-7, 10-13, 20, 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton (U.S. Patent # 5, 786,227) as applied to claims 1-7, 10-12, 20 above and in further view of arguments below. Claims 13 and 23 limit that there must be more than one caspase inhibitors in the apparatus. The M.P.E.P. § 2144.06 states

> "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form

> a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Therefore it is *prima facie* obvious to one of ordinary skill in the art to add more caspase inhibitors to the apparatus of Charlton.

Also while Charlton does teach that the sodium azide in their separation component is dry but not necessarily lyophilized. However, one of ordinary skill in the art would recognize that the simply having dried sodium azide is close enough to having lyophilized azide since the chemical properties would predictably be similar and thus obvious (M.P.E.P. § 2144.09).

Also Charlton teaches that their apparatus is for handling biological samples such as blood (col 1, lines 28-30). It would have been obvious to someone skilled in the art to add a known anticoaglant such as EDTA, Citrate, or heparin to the tube of the apparatus since this is a known technique to improve the storage of blood (KSR International Co. v. Teleflex Inc., 550 U.S.--, 82 USPQ2d 1385 (2007)) .

Therefore the references listed above renders obvious claims 1-7, 10-13, 20, 22-27.

Claims 1-13, 20, 22-27 rejected under 35 U.S.C. 103(a) as being unpatentable over Charlton as applied to claims 1-7, 10-13, 20, 22-27 above, and further in view of Dengen et al (U.S. Patent # 5788862).

The description and rejection of claims 1-7, 10-13, 20, 22-27 are listed in the 35 U.S.C § 103(a) rejection above. Claims 8 and 9 are to the separating member being a gel. Furthermore the claim 9 limits that the stabilizing agent is now separate from the gel separating member.

Charlton teaches the separating member of their invention (filter) to separate blood is a porous plug but not a gel. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Degen et al. They teach that their membrane filter is a gel (Degen, col 8, lines 10-15) and can also be used to filter blood (Degen, col 12, lines 5-8). Since both filters taught by Degen et al. and Charlton can be used to filter blood, it would have been obvious to someone skilled in the art that this is the simple substitution of known membranes used for the same purpose and will predictably achieve the same result (KSR International Co. v. Teleflex Inc., 550 U.S.--, 82 USPQ2d 1385 (2007)).

Also Charlton teaches that their caspase inhibitor (sodium azide) is integrated into their filter they do not teach that the two are separated. However Charlton teach that the azide is there to mix with the biological sample. One of ordinary skill in the art would recognize that the azide would have the same effect if added to the tube itself and not integrated to the filter, since the chemical properties of the azide would remain unchanged. The act of making components of an apparatus integral or separable are matters of obvious engineering choice by the inventors (M.P.E.P. § 2144.04 V).

Therefore the references listed above renders obvious claims 1-13, 20, 22-27.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

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